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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,674	12/31/2003	Douglas R. WARE	05233.0009.NPUS01	1673

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EXAMINER
LILLING, HERBERT J

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/707,674	WARE ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *6-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 9-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6-8* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of the election response filed August 28, 2006.

2. Claims 1-41 are pending in this application.

3. Applicant has elected with traverse Group I, claims 1-15, drawn to a **First method** for reducing the pathogen content of a meat product, the method comprising contacting the meat product with at least one lactic acid producing microorganism, wherein the meat product is unprocessed meat, fish, shellfish, or a processed meat material, classified in class 424, subclass 93.45.

However, in view of the art of record and the persuasive arguments, the restrictions have been withdrawn.

The elections of various species have been maintained.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-41 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

comprises a Lactobacillus acidophilus microorganism selected from the group

consisting of M35, LA45, LA51, L411, NPC 747, NPC 750, D3, and L7.

U.S. Patent Rules of Deposits

It is apparent that the above strain(s) is (are) required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the specific strains. See 37 C. F. R. 1.802.

The specification does not provide a repeatable method for obtaining the specific strain(s) and it does not appear to be a readily available material. Deposit of would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty **and that all restrictions** imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

b) all restrictions imposed by the depositor on the availability to the public of the deposited material **will be irrevocably** removed upon the granting of a patent;

c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function n the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

Please note that the mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 9-15 and 16-41 which are drawn to the elected species are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Garner et al U.S. 7,063,836.

The reference discloses the following, which anticipates the claimed inventions:

Brief Summary Text (5):
Extreme health risks result when humans consume pathogens in contaminated food products such as sprouts, lettuce, meat products, unpasteurized milk and juice, and sewage-contaminated water, for example. The problem is particularly prevalent in the beef and dairy industry. Pathogens present on a cow's udder or on milking equipment may find their way into raw milk. Meat can become contaminated during slaughter, and pathogenic organisms can be mixed into large quantities of meat when it is ground. **When humans eat meat, especially ground beef**, that has not been cooked sufficiently to kill any pathogens present in the beef, serious and life-threatening infections can result. This is a difficult problem to solve because contaminated meat often looks and smells perfectly normal. Furthermore, the number of pathogenic organisms needed to cause disease is extremely small, thus making detection extraordinarily difficult.

Brief Summary Text (7):
Reduction of risk for illnesses due to food borne pathogens can be achieved by controlling points of potential contamination. The beef industry has recognized the need to investigate pre-harvest control of pathogens, particularly E. coli O157:H7, due to potential runoff contamination, contact with humans, and the transfer of pathogens during meat processing. In particular, undercooked or raw hamburger (ground beef) has been implicated in many documented outbreaks as containing E. coli O157:H7.

Brief Summary Text (8):
Accordingly, there is a recognized need for compositions and methods for reducing or eliminating the growth of enteropathogens such as **E. coli O157:H7** for the health benefits to the

animals. Furthermore, there is an important need for reducing or eliminating the growth of enteropathogens in meat and milk producing animals prior to their harvest for the benefit of consumers. By such reduction or elimination in food animals, consumers of beef, dairy, and other food products will be better protected from the risk of consuming such pathogens.

Brief Summary Text (19):
The present invention provides methods and compositions for reducing or eliminating the growth of pathogens in the gut of an animal. In vitro and in vivo tests have been conducted utilizing certain strains of microorganisms, which have been found to be particularly effective at inhibiting the growth of many pathogens, including E. coli O157:H7. As used herein, the term "pathogens" refers to any bacterium that produces a harmful effect in a host animal, and especially those bacteria that infect meat and dairy animals and subsequently infect the human food supply, thus causing disease in humans. The invention is considered to be useful in preventing the growth of a wide variety of pathogenic organisms, as demonstrated herein by several tests showing the inhibition of growth of pathogenic bacteria including E. coli, Salmonella spp., including Salmonella typhirium, and Staphylococcus aureus.

Brief Summary Text (20):
The formulations and methods described herein are applicable to a wide variety of animal species and commercial practices. The inhibition of pathogens in the GIT of animals may be considered for those used in the commercial production of meat, milk, poultry, and fish. In one aspect, the invention includes a method for treating an animal to inhibit the incidence and growth of E. coli O157:H7. The treatment method includes administering a therapeutically effective amount of a selected Lactobacillus acidophilus to an animal that inhibits in vivo growth of E. coli O157:H7. As used herein, the term "therapeutically effective amount" refers to the quantity of bacteria administered to an animal that results in a therapeutic effect by creating an inhospitable environment for pathogens. It has been found that a therapeutically effective amount of **Lactobacillus acidophilus can be as little as 1.times.10.sup.6 CFU/day** when it is administered in combination with other components, although it is preferable that the lactic acid producing bacteria of the invention are administered in an amount of greater than 1.times.10.sup.8 CFU/day. It has been found to be particularly

effective when the selected **Lactobacillus acidophilus** is administered at a level of approximately 1.times.10.sup.9 CFU/day.

Brief Summary Text (24):
The present invention identifies several naturally occurring organisms that are capable of inhibiting pathogen growth within the GIT of an animal. Since many pathogens are acid resistant and populate many distinct areas of an animal's digestive tract, the naturally occurring organisms of the invention are preferably capable of inhibiting pathogen growth at a lower pH and in several areas of the GIT; e.g., the rumen, small intestine and large intestine. Earlier research has shown that **E. coli O157:H7** populations may be decreased in cattle by feeding hay rations, which in and of itself increases rumen pH to 7.0. However, this has limited application in the finishing or feedlot industries since animals in this phase of the production process are typically fed a diet that has a greater proportion of grain in order to foster better **carcass** characteristics.

Description Paragraph (13):
In the following in vivo studies, ruminants were inoculated by providing a sufficient quantity of the bacterial strains tested along with necessary growth medium components to the ruminants' intestines by normal ingestion. Inhibited growth of pathogens such as E. coli O157:H7 were observed in feedlot and **dairy cattle**, as well as other ruminants such as sheep, goats and game. Various inoculation processes were utilized. Examples of these inoculation processes include: Placing lyophilized cultures in water, and then spraying or blending the mixture onto the feed of the animal. The mixture can be in dry form, together with additional carriers that are added to the diet of the animal. The diet can include one or more ingredients such as corn, cereal grains, corn byproducts, cereal grain byproducts, alfalfa hay, corn silage, small grain silage, grass hay, plant stalks, oilseed byproducts, protein meals, urea, minerals, molasses, and various fat and oil products. Suspending lyophilized cultures in various oils, water and/or compounds for providing a drench to be supplied directly to the animal and the digestive tract of the animal. Adding the lyophilized cultures to the drinking water of the animals.

The reference clearly discloses each and every element as claimed in the instant claimsas noted above in bold.

6. **No claim is allowed.**

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918** and **Fax Number** is (703) 872-9306 or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit **1651**
September 09, 2006

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